K033010 1/2

BRAINZ
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OCT 1 0 2003

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8 September, 2003

510(k) Summary of Safety and Effectiveness Information

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92:

(a)(1) Refer to information above and concluding this summary.

(a)(2) Name of the Device

Model No. / Name: **BRM2 Brain Monitor**

Classification Name: Electroencephalograph
Neurology Devices, 21 CFR §882.1400, Class II, OLT, OMC, GKY

(a)(3) Identification of Legally Marketed Devices

K030489	BRM2 Brain Monitor	Brainz Instruments Ltd
K960732	HydroSpot EEG Electrode Model 1501	Physiometrix Inc
K911529	Bunny Electrode / Stealth Electrode	Lead-Lok Inc
K000206	PALS Neonatal Pediatric ECG Electrode	Axelgaard Manufacturing Co Ltd

(a)(4) Description of the Device

The BRM2 Brain Monitor is a two-channel EEG device, consisting of skin electrodes, Sensor Lead, Acquisition Unit, Isolation Unit, Serial and Power Cables, Monitor, and Roll-Pole. All components other than the skin electrodes and Sensor Lead are the same as described in 510(k) K030489 for the BRM2 Brain Monitor.

Changes to the BRM2 Brain Monitor consist of using the Neonatal Sensor Set for the EEG skin electrodes, which has two signal electrode pairs and a reference electrode all pre-wired to a single connector. The Sensor Lead has been modified to add a compatible connector for the Neonatal Sensor Set. Products used for skin preparation at the EEG electrode application sites have been made available in a convenience kit.

(a)(5) Statement of the Intended Use

The BRM2 Brain Monitor is an Electroencephalograph as per 21 CFR §882.1400.
It is used to measure and record the electrical activity of a patient's brain, obtained by placing electrodes on the head. Refer to the Indications for Use statement for further information.

(a)(6) Technological Characteristics Summary

The technological characteristics of the BRM2 Brain Monitor are equivalent to the predicate devices listed above. The EEG monitor system is the same as described in 510(k) K030489 for the BRM2 Brain Monitor. The Neonatal Sensor Set is equivalent in terms of materials and construction to the electrode predicate devices.

(b)(1) Discussion of the Non-Clinical Tests

Non-clinical testing of the BRM2 Brain Monitor has been carried out to cover the changes to the system, including verification of electrical safety and performance, biocompatibility, and product shelf life.

The BRM2 Brain Monitor and Neonatal Sensor Set meet the requirements of IEC 60601-1 general safety international standard. They meet relevant USA deviations of the UL 2601-1 standard for general safety, and particular requirements of the IEC 60601-2-26 standard for electroencephalographs.

The Neonatal Sensor Set meets the requirements of the AAMI EC12 standard for disposable ECG electrodes, and FDA / IEC requirements for safety of electrode lead wires.

(b)(2) Discussion of the Clinical Tests

Clinical testing was carried out to demonstrate the effective duration of use for the Neonatal Sensor Set. This established acceptable performance in general use of the electrodes and in particular over the 24-hour maximum recommended usage period.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

The testing carried out for the BRM2 Brain Monitor and Neonatal Sensor Set indicates that they meet design and performance requirements. The subject device continues to meet the requirements of IEC and UL medical electrical equipment standards for safety, and the IEC particular standard for electroencephalographs. The Neonatal Sensor Set meets appropriate performance requirements for ECG electrodes, and effectiveness was demonstrated in a clinical evaluation.

This information indicates that the BRM2 Brain Monitor and Neonatal Sensor Set are equivalent to the predicate devices in terms of safety, effectiveness and performance.

signed: _____ date: 8 Sept 2003

Chris Mander
Regulatory & Quality Manager
Brainz Instruments Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Brainz Instruments Ltd.
c/o Ms. Denise L. Klinker
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, California 95050-4169

APR - 9 2012

Re: K033010
Trade/Device Name: Model BRM2 Brain Monitor with Neonatal Sensor Set
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLT, OMC, GXY
Dated (Date on orig SE ltr): September 25, 2003
Received (Date on orig SE ltr): September 26, 2003

Dear Ms. Klinker:

This letter corrects our substantially equivalent letter of October 10, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Keoia Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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[510(k)] Number: _____

Brainz Instruments Ltd - BRM2 Brain Monitor

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Brainz Instruments Ltd **BRM2 Brain Monitor** is an Electroencephalograph as per 21 CFR §882.1400 (a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head).

The **BRM2 Brain Monitor** is intended to monitor the state of the brain by acquisition of electroencephalogram (EEG) signals, in the intensive care unit, operating room, and for clinical research.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033010

Prescription Use
(Per 21 CFR §801.109)